K100703

510(K) SUMMARY

[as required by 807.92(c)]

DEC 21 2010

A. 510k Number:

B. Applicant:

Company name: PATS CORP
Address: 49 Candlewood Way, Buena Park, CA 90621, USA
Contact person: Mr Brandon Choi
Phone: 714-523-1592 Fax: 714-523-1592

C. Proprietary and Established Names: COMED CO LTD
Address: #58, Hakdong-Ri, Chowol-Eup, Gwangju-City, Gyeonggi-Do, Korea

D. Regulatory Information

Classification : Class II
CFR cord : 892.1680,
Regular Name : Stationary X-ray system
Product cord : MQB

E. Intended Use

The ATLAS is integrated into the user`s stationary radiography system. This typical configuration permits a qualified/trained doctor or technicolgosist to take a range of head-to-toe diagnostic radiographic exposures of the skull, spinal column, chest abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient. Applications can be performed with patient sitting, standing of lying in the prone or supine positions in an integrated system.
The ATLAS is not intended for mammography.

F. Device Description

The Atlas is provided high resolution radiographic images in a digital format without use of film , chemistry, cassettes or expensive imaging plates. With 98% of fill factor in each pixel, there is a maximum efficiency and lower dose required for image capture. It has single CCD detector.

G. Substantial Equivalence Information

1. Predicate Device
   1) Xaminer (K061595)
   2) QXR-9 (K073056)

For the technological characteristics the Company is relying on the above mentioned

ATLAS. COMED Co., Ltd. believes that ATLAS is substantially equivalent in intended use, principles of operation, and technological characteristics to the predicate devices presented above and any differences with Xaminer (K061595), QXR-9 (K073056) do not raise new types of safety or effectiveness issues, as further discussed below.

2. Comparison with predicate

Model Name	ATLAS	Xaminer	QXR-9
510K Number	Not yet	K061595	K073056
Classification	Class II Device / MQB (21 CFR 892.1650)	Class II Device / MQB (21 CFR 892.1650)	Class II Device / MQB (21 CFR 892.1650)
INTENDED USE	The ATLAS is integrated into the user's stationary radiography system. This typical configuration permits a qualified/trained doctor or technicolgosist to take a range of head-to-toe diagnostic radiographic exposures of the skull, spinal column, chest abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient Applications can be performed with patient sitting standing of lying in the prone or supine positions in an intergrated system. The ATLAS is not intended for mammography	The Xaminer (510k submission device) is integrated into the user's stationary radiography system. This typical configuration permits a qualified/trained doctor or technologist to take a range of head-to-toe diagnostic radiographic exposures of the skull, spinal column, chest abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions in an integrated system. The Xaminer (510k submission device) is not intended for mammography	QXR-9 Digital Radiography system is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.
Feature	The Atlas is provided high resolution radiographic images in a digital format without use of film , chemistry, cassettes or expensive imaging plates. With 98% of fill factor in each pixel there is a maximum efficiency and lower dose required for image capture. It has single CCD detector	The Xaminer is the latest version of Xplorer digital radiographic detectors. It includes features and functions that have been developed since the introduction of the original Xplorer 1000 (predicate device). Xaminer provides high resolution radiographic images at 3.2 lp/mm in a digital format without use of film, chemistry, cassettes or expensive imaging plates. With 98 % of fill factor in each pixel there is a maximum efficiency and lower dose required for image capture. It has single CCD detector with 9 mega pixel digitized at 14 bits per pixels	The QXR-9 Digital Radiography Systems is a high-resolution digital imaging system designed for digital radiography. It is designed to replace conventional film radiography techniques. This system consists of Detector, Power Supply Unit, Accessories, and S/W. The S/W is operated at a workstation that is using Windows XP based OS as its operating system. The system allows the operator to acquire and display images(Image size : 3072x3072 pixels) on 1600 x1 200 high resolution monitor. Various features of S/W such as image inversion, image processing, zooming, panning, window level adjustment, contrast adjustment etc enable the operator to view diagnostic details difficult to see using conventional non-digital techniques.
STANDARD	EN ISO 14971 EN 60601-1 EN 60601-1-4 EN 60601-1-2	EN ISO 14971 EN 60601-1 EN 60601-1-4 EN 60601-1-2	EN ISO 14971 EN 60601-1 EN 60601-1-2
Sensor	CCD+ scintillator	CCD- scintillator	CCD- scintillator
Imaging Pixels	3,103 x 3,085(9 Megapixel)	3,072 x 3,072 (9 Megapixel)	3,072 x 3,072 (9 Megapixel)

Active Image Size	17" x 17"	43 cm x 43 cm (17" x 17")	43 cm x 43 cm (17" x 17")
Pixel Size	144 microns	144 microns	144 microns
Nyquist Resolution	3.5 lp/mm	3.2 lp/mm	3.5 lp/mm
Bit Depth	16Bit capture	14 bit capture	14 bit capture
Fill Factor	98%	100%	<<
Preview Image	Less than 5 seconds	Less than 5 seconds	Less than 3.5 seconds
Imaging Detector Weight	45kg~50Kg	75 kg (165 lb)	<<

3. Conclusion

Based on the above, we conclude that the Digital X-ray Detector ATLAS has substantial equivalent intended use as the-market-cleared Xaminer (K061595), QXR-9 (K073056) and has substantial equivalent technological and performance characteristics. After analyzing both bench as well as laboratory testing to applicable standards, it is the conclusion of ATLAS is as safe and effective as the predicate devices, has few technological differences, but there are no new indications for use and without raising any new safety and/or effectiveness concerns.

Consequently, it is clear that it substantially equivalent to the predicate devices.

H. Performance Characteristics (If/when applicable)

Applied by standard of

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- IEC 980:2003, Graphical symbols for use in the labeling of medical devices
- IEC1041:1998, Information supplied by the manufacturer with medical devices
- ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 14155-1:2003, Clinical investigation of medical devices for human subjects - Part 1: General requirements
- ISO 14971:2007, Medical devices - Application of risk management to medical devices
- IEC 60601-1 Medical electrical equipment - Part 1:General requirements for safety (IEC 60601-1:1988/A1:91/A2:95)
- IEC 60601-1-2:2001/A1:2006, Medical electrical equipment - Part 1: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-4:1996+A1:1999:1999, Medical electrical equipment. Part 1-4: General requirements for safety- Collateral standard: Programmable electrical medical systems

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

COMED Co., Ltd.
c/o Mr. Brandon Choi
Representative
PATS Corporation
49 Candlewood Way
BUENA PARK CA 90621

DEC 21 2010

Re: K100703
Trade Name: ATLAS (Digital X-Ray Detector)
Regulation Number: 21 CFR § 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MBQ
Dated: November 5, 2010
Received: November 10, 2010

Dear Mr. Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

DEC 21 2010

510(k) Number (if known): K100703

Device Name: ATLAS (Digital X-Ray Detector)

Indications For Use: The ATLAS is integrated into the user's stationary radiography system. This typical configuration permits a qualified/trained doctor or technologist to take a range of head-to-toe diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions in an integrated system.

The Atlas is not intended for mammography.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100703